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WOMEN'S HEALTH
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ANNUAL REPORT

DES PUBLIC EDUCATION AND DIAGNOSTIC SERVICES PROGRAM

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Michael S. Dukakis, Governor
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INTRODUCTION

In accordance with Chapter 784, of the Acts of 1981, the Department of Public Health undertook the development of a comprehensive program designed to alert the citizens of the Commonwealth to the potential health effects of exposure to diethylstylbestrol (DES), provide for accessible diagnostic services for those at risk for exposure, and educate the state's medical care providers in this issue.

This report is submitted to the Legislature in fulfillment of legislative requirements. It provides a detailed overview of the Department's efforts for DES education and diagnostic services, and the background information necessary for a full understanding of the complex public health problems created by the widespread use of this drug in the Commonwealth.

The report is organized in the following manner:

Section I	describes the enabling legislation in detail and presents a brief historical overview of the process by which it was enacted.
Section II	reviews the use of DES in Massachusetts, and analyses the potential at-risk population of DES-exposed children, and women who were administered DES during their pregnancies.
Section III	describes in detail the Department's public information and education campaigns and ongoing activities to increase the awareness of the potential risks of DES-exposure. Also included in this section is a description of the mechanism developed to ensure broad-based access to up-to-date information through the Cancer Information Service.
Section IV	describes the Department's diagnostic services program. Included here is a detailed discussion of the clinical manifestions of DES exposure, as well

as a description of the mechanism through which services are available to all at-risk persons. A preliminary analysis of initial client data is included.

Section V	reviews the Department's professional education activities targeted to the medical community's awareness of DES-related health problems and its sensitivity to the needs of the at-risk population.
Section VI	presents the Department's recommendations for continued program activities.

The Department believes it has, with minimal financial support, developed a comprehensive program as required by the Legislature that will provide accurate and accessible information and diagnostic services to all residents of the Commonwealth at risk for exposure to DES. During the first year of the operation of the program, we have experienced cooperative and productive support from all sectors of the community. As a result of the coordinated efforts of the Advisory Board, the media, the medical community and the various Department units involved in this program, we are able to report favorably on our progress to date.

The Department would like to express its gratitude to the members of the DES Program Advisory Board, the staff of the Divisions of Preventive Medicine and Family Health Services, and both the Boston Women's Health Book Collective and the Cancer Information Service for their assistance in making this program a reality.

We give special thanks to Mrs. Pearl K. Russo, Senior Medical Writer, for her assistance in the preparation and editing of the text.

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I. DES LEGISLATION IN MASSACHUSETTS

Legislation addressing the concerns of persons exposed to diethylstilbestrol (DES) was first filed by Senator Sharon Pollard in 1979 as S.451. The bill was modeled after a recently passed law in the State of New York, which also has a large DES-exposed population. Despite the support of the Massachusetts Caucus of Women Legislators, the Governor's Commission on the Status of Women, the DES Action Project, the National Cooperative Diethylstilbestrol Adenosis (DESAD) Project and National Organization for Women, S.451 died in the House Ways and Means Committee that year.

Senator Pollard refiled a modified version of the legislation, S.559, in 1980. The bill died in prorogation while awaiting final approval by the House and Senate. However, language was successfully inserted into the budget for fiscal year 1981 during that session, under item #4513-1000. This new budget language mandated a DES informational and educational program, as well as diagnostic evaluations, to be administered by the Department of Public Health.

A carefully revised version of the bill, S.651, was resubmitted by Senator Pollard in 1981. With the impressive support of the Women's Legislative Caucus, the DES Action Project, and a number of committed individuals, including Representative Elizabeth Metayer, the legislation was signed into law on December 14, 1981 as Chapter 734 of the Acts of 1981. Additionally, language mandating that the Department of Public Health administer a DES public informational and educational program and diagnostic evaluations was included in the budget for fiscal year 1982.

In 1982, House Speaker Thomas McGee appointed Representative Metayer to serve on the DES Advisory Board. Thanks to the efforts of the Massachusetts Caucus of Women Legislators, the DES Action Project, and many sympathetic legislators, the budget battle for fiscal year 1983 resulted in a $90,000 appropriation for the state DES program ($40,000 for an informational and educational campaign and $50,000 for diagnostic evaluation).

DES legislation in Massachusetts, designated "An Act Establishing a Public Information Program Relative to Diethylstilbestrol (DES)," became effective in 1981 as Chapter 734, Acts of 1981, Massachusetts General Laws.

Under provisions of the act, the Massachusetts Department of Public Health has been designated to:

1. Establish, promote and maintain a public education program.

2. Determine regional diagnostic evaluation centers for women who were exposed to DES during pregnancy and their offspring who were exposed prenatally. These medical facilities will receive financial reimbursement for providing specialized diagnostic evaluations for DES daughters.

3. Encourage people to seek medical care for the prevention or treatment of any malignant conditions resulting from exposure to DES.

4. Provide training programs to instruct physicians and nurses at each diagnostic evaluation center.

The act prohibits health and life insurance companies from discriminating against the DES-exposed by cancelling coverage, developing restrictions or imposing excessive rates. "The practices under this section shall include not only those overtly discriminatory, but also practices and devices which are fair in form, but discriminate in practice."

Under provisions of the act, an Annual Report to the Legislature will be submitted by the Department of Public Health to cover its findings and recommendations about the DES program.

In addition, an Advisory Board will be established consisting of five members. The Advisory Board has added several members in 1982 to enhance communication and improve overall program coordination.

II. DES USE IN MASSACHUSETTS: A HISTORY AND NEEDS ASSESSMENT

A History of DES Use:

Diethylstilbestrol (DES), the synthetic nonsteroidal estrogen, was first produced in London in 1938 by Dodds and his colleagues.[1] It was used extensively during the late 1940's and early 1950's in the United States after publication of reports on the efficacy of its use during pregnancy to prevent miscarriages and premature births, and to treat diabetes and toxemias.[2] In 1953, Dieckmann and his associates reported the results of a controlled clinical trial of DES during pregnancy. They concluded that DES did not reduce the incidence of miscarriages, prematurity, postmaturity, perinatal mortality, or toxemias. A 1978 re-analysis of the data from the Dieckmann study showed that DES had actually increased spontaneous abortion, neonatal deaths, and premature births.[4]

Although the use of DES in pregnancy declined after the Dieckmann report, physicians continued to prescribe the hormone to many women until 1971. In that year, a series of studies showed an association between in utero exposure to DES and the subsequent development of clear-cell adenocarcinoma of the vagina or cervix.[5,6] (Such patients are usually designated DES daughters and DES mothers.) Estimates are that the incidence of clear-cell adenocarcinoma will be between 1.4 per 1,000 and 10,000 women through age 24.[7] In the past, such cancers had been reported only sporadically, and then in older women. Several reports have noted an increase in the prevalence of nonmalignant abnormalities in DES daughters, including vaginal adenosis, cervical collars, cervical erosion, cervical hypoplasia, cockscomb cervix, transverse ridges, and hypoplastic and T-shaped uterus.[8-13] Estimates of the number of DES daughters with adenosis range from 30 to 97 percent. In the general population not exposed to DES, adenosis occurs in only about 4 percent of women.

Sufficient information is not yet available to document fertility rates, pregnancy outcomes, or long-term effect on offspring of DES mothers; however, menstrual complaints and fertility problems have been reported to occur more frequently in DES daughters than in the general population. Although some investigators[10] have found an increased number of anatomical abnormalities in the upper reproductive tract of DES daughters, the extent to which the study of Kaufman and colleagues reflects the degree of such anomalies in all DES-exposed subjects remains to be

determined. Although disagreements have surfaced in the medical community about the nature of the problems, the consensus is that DES daughters do suffer some inability to conceive (infertility), and have repeated miscarriages, incompetent cervixes, ectopic pregnancies, and premature deliveries resulting in stillbirths.[14] No information is available to suggest that children born to DES daughters have birth defects or other abnormalities.

Concern has also begun to grow among mothers who had taken DES during pregnancy and among sons (designated DES sons) who had been exposed in utero to DES. Preliminary studies suggest an increased risk of testicular cancer among men with undescended testes, although no testicular cancers have been associated with DES exposure to date. Recent reports[15] clearly show an excess of genital abnormalities, but as yet no definitive information on the fertility implications of these findings has been published. Benign abnormalities in DES sons include epididymal cysts, hypospadias, microphallus, indurations and varicoceles of the testicles, urethral strictures and other urinary tract abnormalities, sperm and semen abnormalities, and undescended and hypoplastic testicles.

Although a statistically significant relationship between the use of DES during pregnancy and the risk of cancer in DES mothers has not been established, experimental animal studies, studies of other estrogenic compounds, and a 25-year follow-up on the subjects of the Dieckmann study, all reflect a serious concern about the carcinogenic potential of DES in these mothers.[16] However, a follow-up study of women seen at the Mayo Clinic, who had received smaller doses of DES than what the women in the Dieckmann study had received, did not show an increase of breast cancer among DES mothers.[17] The negative findings of the Mayo Clinic study indicate that the evidence was insufficient to conclude that the use of DES during pregnancy causes breast cancer in the mother. Although a definite relationship between DES during pregnancy and the risk of cancer in the mothers is uproved, it is suspect.

Despite the fact that the Food and Drug Administration (FDA) has outlawed the use of DES during pregnancy, DES is still being prescribed in vast quantities for a variety of purposes. These include estrogen replacement in cases of hormone deficiency, prevention and treatment in selected cases of advanced breast and prostate cancer, suppression of lacatation in new mothers who do not breast feed their infants (as of 1972 more than 40 million women had been given DES as a lactation suppressant[18]), and as a postcoital contraceptive (the "morning-after" pill).

It was not until 1979 that the FDA permanently banned the use of DES as a growth stimulant in cattle. DES had been implanted in pellet form in chickens and cattle and used as feed since the early 1940's. (The FDA had banned DES pellets implanted in the necks of chickens in 1959, when dangerously high levels of the drug were found in the consumable flesh of the birds--but similar implants in cattle were allowed for 20 years more). DES is still used by feedlot owners. In 1980 FDA inspectors found nearly half a million head of cattle illegally implanted with DES pellets and more than 1,200 cattle that had been illegally fed DES.[15]

REFERENCES

1. Dodds EC, Goldberg L, Lawson W, Robinson R. Estrogenic activity of certain synthetic compounds. Nature. 1938; 141:247-8.

2. Smith WO. Diethylstilbestrol in the prevention and treatment of complications of pregnancy. Am J Obstet Gynecol. 1948; 56:821-34.

3. Dieckmann WJ, Davis ME, Rynkiewicz LM, Pottinger RE. Does the administration of diethylstilbestrol during pregnancy have therapeutic value? Am J Obstet Gynecol. 1953; 66:1062-81.

4. Brackbill Y, Berendes HW. Danger of diethylstilbestrol: review of a 1953 paper. Lancet. 1978; 2:520.

5. Herbst AL, Ulfelder H, Poskanzer DC. Adenocarcinoma of the vagina: association of maternal stilbestrol therapy with tumor appearance in young women. N Engl J Med. 1971; 284:878-81.

6. Grennwald P, Barlow JJ, Nasca PC, Burnett WE. Vaginal cancer after maternal treatment with synthetic estrogens. New England Journal of Medicine 1971; 285:390-2.

7. Herbst, AL, Cole P, Colton T, Robboy SJ, Scully RE. Age-incidence and risk of diethylstilbestrol-related clear-cell adenocarcinoma of the vagina and cervix. Am J Obstet Gynecol. 1977; 128:43-50.

8. Herbst AL, Scully KW, Robboy SJ. Prenatal diethylstilbestrol exposure and human genital tract abnormalities. Natl Cancer Inst Monogr. 1979; 51:25-35.

9. Bibbo M, Gill WB, Azizi F, et al. Follow-up study of male and female offspring of DES-exposed mothers. Obstet Gynecol. 1977; 49:1-8.

10. Kaufman RH, Binder GL, Gray PM, Adam E. Upper genital tract changes associated with exposure in utero to diethylstilbestrol. Am J Obstet Gynecol. 1977; 128:51-9.

11. Haney AF, Hammon DB, Soules MR, Creasman WT. Diethylstilbestrol-induced upper genital tract abnormalitis. Fertil Steril. 1979; 31:142-6.

12. O'Brien PC, Noller KL, Robboy SJ, et al. Vaginal epithelial changes in young women enrolled in the National Cooperative Diethylstilbestrol Adenosis (DESAD) Project. Obstet Gynecol. 1979; 53:300-8.

13. Robboy SJ, Koufman RH, Prat J, et al. Pathologic findings in young women enrolled in the National Cooperative Diethylstilbestrol Adenosis (DESAD) Project. Obstet Gynecol. 1979; 53-309-17.

14. Herbst AL, Hubby MM, Blough RR, Azizi F. A comparison of pregnancy experience in DES-exposed and DES-unexposed daughters. J Reprod Med. 1980; 24:62-9.

15. Orenberg, CL. DES: The Complete Story New York: St. Martin's Press, 1981; 82- 9.

16. Bibbo M, Haenszel WM, Wied GL, Hubby M, Herbst AL. A twenty-five year follow-up study of women exposed to diethylstilbestrol during pregnancy. N Engl J Med 1978; 298:763-7.

17. Fink DJ. DES Task Force summary report. Washington, D.C.: Government Printing Office, 1978. (DHEW Publication No. (NIH) 79-1688).

18. Haire, D. The Cultural Warping of Childbirth. A special issue. International Childbirth Education Association, 1972.

Needs Assessment:

A review of the published information on the number of DES daughters in the national population reveals that the precise number has not been determined. Various independent medical researchers have, however, extrapolated a gross national estimate ranging from 500,000 to 2,000,000.[1-5] No survey has been conducted either by independent researchers or by any governmental or public health agency to determine the number of DES daughters currently residing within the State of Massachusetts. If one assumed that the geographical distribution of DES daughters were spread evenly among the 50 states in proportion to the percentage of the national population residing in each state, one could extrapolate from the percentage of the national population a figure for the number of Massachusetts DES daughters.

If the 1977 figure of 2.67% (percentage of United States resident population residing in Massachusetts) is used,[6] the estimate for the number of Massachusetts DES daughters ranges from 13,350 (2.67% of 500,000, the low nationwide estimate of DES daughters) to 53,400 (2.67% of 2,000,000, the high nationwide estimate of DES daughters).

According to a second study,[7] the total number of DES-exposed persons range from 2.7 to 5.4% of the population. Of the total Massachusetts population of 5,737,037, the range of DES-exposed persons would therefore be from 154,899 to 309,799. Half of the exposed population would represent mothers--77,449 to 154,899; one-fourth would represent daughters--38,724 to 77,449; and one-fourth would represent sons--38,724 to 77,449.

REFERENCES

1. DES Task Force Summary Report, United States Department of Health, Education and Welfare, Public Health Service, National Institutes of Health, (DHEW Publication No. (NIH) 79-1688), 1978; 31.

2. Noller K. Diethylstilbestrol usage: its interesting past, important present, and questionable future. Med Clin N Amer. 1974; 58:793-8.

3. LaBarthe D,et al. Design and preliminary observations of National Cooperative Adenosis (DESAD) Project, Obstet Gynecol. 1978; 51:543.

4. Poskanzer D, Herbst A. Epidemiology of vaginal adenosis and adenocarcinoma associated with exposure to stilbestrol in utero. Cancer 1977; 39:1982-3.

5. Ulfelder H. The stilbestrol-adenosis carconoma syndrome. Cancer 1976; 38:426-9.

6. United States Department of Commerce, Bureau of the Census. Current Population Reports, Series P-20, No. 324. Population Characteristics, Population Profile of the United States 1977. April 1978, p. 34.

7. Adess N, Cody P. Community organizing for health: A DES action manual. Coalition for the Medical Rights of Women, San Francisco, 1980.

III. PUBLIC INFORMATION & EDUCATION COMPONENT

The Division of Preventive Medicine (DPM) is responsible for promoting public knowledge about DES and encouraging individuals who were exposed to use available diagnostic services.

A comprehensive Public Health education campaign has been directed to physicians and other health professionals, as well as to the general public. It has targeted health facilities, women's organizations, pharmacies, libraries, and other community groups, and made use of television, radio, and newspapers. Additionally, a group of health care providers and DES-exposed mothers, daughters, and sons are available for public-speaking engagements.

The 1982 campaign was kicked off with a press conference at the State House attended by Senator Pollard, Representative Metayer, DES Action, Dr. Ann Barnes, and others who had been involved in passing the DES legislation, including the Commissioner of Public Health, Alfred L. Frechette. M.D., M.P.H.

The Division of Preventive Medicine staff extensively researched several other states' public education campaigns for useful guidelines for the Massachusetts program. Invaluable advice and technical assistance were provided by the New York State Health Department, DES Action, and the Maine Department of Human Services, Division of Health Education.

DPM Program staff distributed widely posters and brochures, (including information directed to physicians) to all hospitals, clinics, HMO's, and neighborhood health centers. Statewide distribution of posters and brochures in bulk quantity covered unemployment offices (Division of Employment Security), Star Market, Medi-Mart Drug Stores, libraries, local health departments, pharmacies, women's organizations, and community groups. Through a contractual arrangement with the Boston Women's Health Book Collective, Inc., this organization's extensive experience in women's health education provided invaluable support for program activities.

Media coverage was extensive. Staff used television for four public service announcements (three in English, one in Spanish) that were distributed to stations throughout the state. Talk-show interviews were held with Division of Preventive Medicine representatives, and Newsweek video filmed a 30-minute program to be syndicated to 100 cable stations.

Representatives from the Division of Preventive Medicine and DES Action appeared on 15 talk shows throughout the state.

Press releases announcing the campaign were distributed to all daily and weekly newspapers in Massachusetts, and wire services. Approximately, 50 articles were published across the state. DES posters were placed in regional editions of national magazines.

A group of individuals with specific DES-related expertise throughout the state has been established. These people are available for public speaking engagements, news and radio interviews, and other media-related events. The group includes: physicians, DES-exposed mothers, daughters, and sons, the Department of Public Health Program Coordinators (both clinical and public education components), and representatives from the Women's Legislative Caucus.

In cooperation with the Department of Public Health, the Cancer Information Service (CIS), Sidney Farber Cancer Institute, serves as the official clearinghouse for DES information for the Massachusetts DES Information/Education Program. In this capacity, the CIS provides information to the public concerning the history of DES exposure and the potential health risks. Callers are provided with supplemental materials to re-emphasize the information explained by the CIS counselors. In addition, DES-exposed individuals are counseled on the necessary steps to assure appropriate medical evaluation and follow-up. If necessary, the CIS provides medical and legal referrals.

A post office box has also been designated for further requests for information. In 1982, replies and informational materials were sent to writers of 300 letters received by the program.

In addition to the public education activities described above, a concerted effort was initiated soon after passage of the enabling legislation to alert all insurance companies doing business in Massachusetts of the implications of Chapter 734, Acts of 1981, for policy holders and life and health insurance firms. An informational mailing was developed by the Massachusetts Women's Legislative Caucus and distributed by the Division of Preventive Medicine to all affected life and health insurance companies.

DES PUBLIC EDUCATION CAMPAIGN

THEME: DES: The Wonder Drug We Should Wonder About

MATERIALS DISTRIBUTED:

Four-color Poster printed in English and Spanish, with multi-racial subjects

Video-taped television Public Service Announcements in English and Spanish, 10-, 30- and 60-seconds

Taped radio Public Service Announcements in English and Spanish

SUPPORTING HEALTH EDUCATION MATERIALS:

Questions and Answers about DES Exposure During Pregnancy and Before Birth, US Department of Health and Human Services, NIH Publication No. 80-1118, March 1980.

Prenatal Diethylstilbestrol (DES) Exposure: Recommendations of the DESAD Project for the Identification and Management of Exposed Individuals, US Department of Health and Human Services, NIH Publication No. 81-2049, March 1981.

Were You or Your Daughter or Son Born After 1940?, US Department of Health and Human Services, NIH Publication No. 81-1226, March 1981.

You May be a DES Son, DES Action Publication, 1981.

You May be a DES Daughter, DES Action Publication, 1981.

DES Program in Massachusetts, Division of Preventive Medicine publication, Mass. Department of Public Health, 1981.

DES: The Facts, Division of Preventive Medicine publication, Mass. Department of Public Health, 1981.

Ask Your Mother: Finding the DES-Exposed, A Slide-tape presentation, DES Action, 1981.

SUMMARY OF MATERIAL DISTRIBUTION

I. Bulk Distribution:

Harvard Community Health Plan	2,000 Brochures 100 Posters
Mass. League of Community Health Centers	1,500 Brochures 210 Posters
Division of Employment Security Unemployment Offices	7,500 Brochures 120 Posters
Medi-Mart Drug Stores	5,000 Brochures
Star Market	10,000 Brochures
Libraries	3,600 Brochures 60 Posters

II. Clinic Distribution:

170 Hospitals	3,400 Brochures 170 Posters 170 Physician Brochures
200 Clinics	4,000 Brochures 200 Posters
75 Neighborhood Health Centers	1,400 Brochures 210 Posters

III. Individual Mailings to Women's & Professional Organizations:

(20 Brochures & 1 Poster)

TOTAL	600
College Women's Centers	13
University Women's Centers	20
Women's Health Clubs	25
Community Colleges	16
State Colleges	16
Women's Colleges	12
Counseling Centers	27

III. Individual Mailings (Continued)

Women's Centers	50
Women's Advocacy	16
Vocational Counseling	16
Vocational Counseling for Women	18
Women's Legal Groups	12
Child Care	10
Sports	25
Religious Organizations	30
Political Action	40
Labor Groups & Unions	10
Business & Professional Groups	18
Women's Shelters	12
Penal Projects	4
DNA Addiction	8
Head Start	37
Alcoholism	9
Government Agencies	7
Government Affiliated Women's Groups	6
Continuing Education	52
Pregnancy Counseling	17
Community Organizations	20
Ethnic Advocacy Groups	16
Neighborhood Community Groups	25
Emergency Shelters	9
Food Co-ops	17

III. Individual Mailings: (Continued)

Gay & Lesbian Organizations	6
Women's Health Clinics	13
Health Care Consumer Groups	6

Information and Referral Summary:

The following summary of data details the DES inquiries handled by the Cancer Information Service (CIS) during 1982.

In the first seven months of the DES Information and Education Program, (May 26 - December 31, 1982) a total of 1,178 DES-related inquiries have been handled by the Cancer Information Service. The calls were most commonly placed by DES mothers (46%) and DES daughters (30%). Fewer calls were placed by DES sons (6%), other DES relatives (5%) and health professionals (17%). The remainder of the inquiries came from individuals determined not to be at risk or for whom the exposure status could not be determined.

The geographic distribution of the calls remained consistent throughout the reporting period. The highest call volumes were generated from Middlesex (31%), Norfolk (17%), and Suffolk (17%) counties.

In the course of the DES program, CIS counsellors have made a number of behavioral suggestions to the callers. The nature of these suggestions has remained consistent throughout the program. DES daughters were most commonly instructed to contact a physician and arrange for an examination. DES mothers and sons, however, were more commonly instructed to contact their physicians to document their exposure status, and to learn breast or testicular self-examination. In adddition, a total of 68 medical referrals were made. Forty-eight (48) referrals were made to DES-designated clinics and an additional 20 were made to local community hospitals (Tables 1,2,3).

The response to the program is consistent with the coverage by the newspaper, radio, and television media. As Table 4 indicates, television public service announcements continue to generate the largest percentage of calls, accounting for 33% of the total call volume.

Table 1. Total Number of DES Inquiries Received in Period May 26 to Dec. 31, 1982.

	Period			Month				Total	%
Exposure Status	5/26-6/30	July	Aug.	Sept.	Oct.	Nov.	Dec.		
DES Mother	381	69	31	9	6	21	26	543	46
DES Daughter	193	50	50	15	6	16	25	355	30
DES Son	35	14	10	1	0	6	5	71	6
DES Other Relative	20	16	9	4	0	5	7	61	5
Health Professional	4	0	0	0	0	0	0	4	1
Other/Unknown *	42	24	8	7	14	27	22	144	12
Total	675	173	108	36	26	75	85	1178	100

* Other/Unknown includes persons determined not to be at risk and persons for whom risk could not be determined.

Table 2. Referrals
Made by Cancer Information Center
May 26 through Dec. 31, 1982.

	Referrals		
Exposure Status	Mass. Community Hospital	DES Clinic	Total
DES Mother	3	15	18
DES Daughter	9	26	35
DES Son	3	0	3
DES Relative	2	4	6
Undetermined	3	3	6

Table 3. Geographic Distribution of DES-Related Inquiries
May 26 through Dec. 31, 1982

County	Number	Percentage
Barnstable	21	4
Berkshire	1	<1
Bristol	8	2
Dukes	0	0
Essex	32	7
Franklin	4	<1
Hampden	10	2
Hampshire	1	<1
Middlesex	147	31
Nantucket	0	0
Norfolk	79	17
Plymouth	30	6
Suffolk	81	17
Worcester	50	11
Total	464	100

Table 4. Source of Calls
May 26 through December 31, 1982.

Source	Number	Percentage
Family/Friend	22	2
Physician	7	1
Health Agency	42	4
TV	369	33
Radio	73	6
Newspaper	183	17
Phonebook Directory Assistance	12	1
SFCI Switchboard	19	2
Poster	20	2
Other	350	32
Total	1097	100

IV. DIAGNOSTIC SERVICES COMPONENT

The Division of Family Health Services assumed responsibility for the establishment of regionally based DES Diagnostic Centers after the passage of the Acts of 1981, Chapter III, Section 4K.

Four major objectives were developed:

1. To establish programs on a regional basis in order to assure geographical access to specialized diagnostic services by exposed persons.
2. To establish a reimbursement procedure in order to assure financial access by exposed persons.
3. To establish programs in facilities with personnel, equipment, laboratory and pathology services that would ensure high quality services to DES-exposed persons.
4. To establish programs designed to allow for continuity of care over a period of years.

A comprehensive review of the literature was undertaken to determine the current status of scientific studies, the known effects of DES exposure on individuals and current recommendations for diagnostic evaluations and continuing care of DES-exposed persons.

The effect of the exposure, appropriate evaluation procedures, and follow-up care was found to differ for each type of DES-exposed person.

The following medical conditions were found in DES daughters:

1. Adenosis - The presence of abnormally placed tissue, depending upon its location, called vaginal adenosis or cervical erosion. This is estimated to occur in up to 80% of all DES daughters. It is a benign condition that does not require active treatment, but periodic regular evaluations are needed.
2. Structural Abnormalities - Structural changes in the vagina or cervix described by a variety of names - hood, rim, collar or coxcomb cervix. These changes are estimated to occur in about one-third of DES daughters.

3. Squamous Metaplasia - A process whereby the adenosis changes gradually over a long period of time (sometimes as long as 20 years) until a mature squamous epithelium is produced. Although generally a benign condition, regular follow-up evaluations are required as there is risk that the condition may become malignant.

4. Dysplasia - A form of abnormal tissue also requiring regular evaluations as it may regress over time or may mature slowly into carcinoma.

5. Carcinoma insitu - A precancerous or localized and curable form of cancer in the very early stage of development. Treatment is by cryosurgery (freezing) or by conization (the coring out of the affected portion of the cervix, but leaving the reproductive organs intact).

6. Clear-Cell Adenocarcinoma - The association between intrauterine exposure to DES and the rare development of vaginal and cervical clear-cell adenocarcinoma, first described in 1971. By 1979 approximately 400 cases of this form of cancer were reported to the Registry for Research on Hormonal Transplacental Carcinogensis in Chicago, Illinois, and from various parts of the world. The ages of girls and women involved ranged from seven to 31. There are approximately 40 to 50 new cases reported annually. Before 1971 this type of cancer was found rarely, and only in older women. Surgery is required to remove the malignancy.

Other possible effects of in utero exposure to DES include menstrual difficulties, ectopic pregnancies, miscarriages and aborted pregnancies.

DES sons may have these medical conditions:

1. Genito-Urinary Abnormalities - Limited studies have been done on the possible effects of interuterine exposure on DES sons. These studies indicate the possibility that DES sons may experience various structural abnormalities, including: epididymal cysts, hypoplasia of the testes, microphallus and cryptorchidism. They may also experience pathological changes in the semen that may result in a lowered reproductive capacity.

2. Cancer - At present, there is no conclusive evidence linking DES exposure and cancer of the genitourinary tract in DES sons.

3. Fertility - At present, no definitive information is available on the implications of the possibility of lowered reproductive capactiy of DES sons.

Mothers of the DES daughters have also been studied. One study reported a slightly higher frequency of breast cancers in exposed mothers than in nonexposed mothers. This finding, however, was based on a very small sample, and the results were therefore not considered statistically significant. Nevertheless, because of this finding, continued, regular surveillance of DES mothers is recommended. Further studies are ongoing to establish if there is, in fact, an increased risk of breast cancer in DES mothers.

An analysis was made, based on the information available, of each one of the three distinct groups of DES-exposed persons, i.e., daughters, sons, and mothers. An attempt was made to determine for each the specific, specialized diagnostic evaluations required to determine status, estimated costs of services, and type of program required to meet anticipated needs. The analysis indicated that the type of services needed by DES daughters differed greatly from that of DES mothers and sons.

A Federal Task Force recommended diagnostic/medical evaluations for the three groups. For DES daughters, the Task Force recommended that initial diagnostic evaluations of known or suspected DES daughters should be performed regularly after menarche or by age 14 if menarche has not occurred. The examination, in addition to the regular gynecological examination and Papanicolaou smear, may also include colposcopy, iodine stain and tissue biopsy.

These evaluations are highly specific and require specialized medical, laboratory, and pathology personnel and equipment to assure an accurate diagnosis of any abnormality, and in particular, the presence of clear-cell adenocarcinoma. DES daughters, even those thought to have normal/benign findings, require, at least, annual examinations to assure the early detection of a malignancy associated with DES exposure.

The Task Force recommendations for DES mothers include breast self-examination, an annual breast exam by qualified medical personnel and, in certain cases, mammography. With the exception of the sometimes recommended mammography, no specialized evaluations or tests are currently recommended.

The Task Force recommends that, in addition to testicular self-examination, all DES sons have a physical examination in order to determine the presence of obvious abnormalities such as undescended or hypoplastic testes. In such a case, referral to a urologist may be made.

In summary, according to current information, there is no "one-time" diagnostic evaluation program that would allow for the identification of DES-related problems in DES mothers and sons. Their needs may be summarized as follows: information and materials to encourage and teach regular self-examinations; knowledge of possible long-term effects of DES exposure to ensure that the primary health care provider is made aware of the history of DES exposure (this is necessary to ensure regular physical examinations that include appropriate procedures); and access to specialized diagnostic and therapeutic services if a DES-related problem is identified.

On the other hand, DES daughters have a documented increased risk of the development of abnormalities and/or carcinoma associated with DES exposure. Therefore, they require specialized diagnostic evaluations that may or may not be available to them through their regular source of primary health care. Particularly crucial is the availability of highly skilled pathology personnel experienced and knowledgeable in analyses of DES specimens.

An attempt was made to project the annual cost of a DES screening program. The cost per examination was projected individually, as the requirements for each group, daughters, sons and mothers, varied so widely. Costs were based on the federal recommendations for medical care. The assessment confirmed the perception that of the three affected groups, DES daughters warranted priority planning because of their need for highly specialized practitioners, laboratory and pathology services. Therefore, the primary focus during the first stage of implementation has been on the development of a regional network of specialized DES Diagnostic Centers in order to ensure access to DES daughters in need of these services.

The focus of activities for mothers and sons during this initial phase of the program development will be on increasing the awareness of DES mothers and sons of the possible health risks associated with DES exposure. The need for regular self-examination as well as regular evaluations by a primary health care provider will be stressed.

Once the regional network of approved DES Diagnostic Centers is firmly established, expansion of the program to include DES mothers who require mammography or other specialized tests will be explored. During the second year of

the program expansion, an attempt will be made to identify at least one site as approved for referral of DES sons in need of a specialized assessment of conditions thought to be associated with DES exposure.

Several program prototypes for DES diagnostic programs for DES daughters were explored. These included: the development of regional screening sites, the development of one centralized program with several satellites, the development of services through a "purchase of service" contract, and the development of several programs throughout the state from which specific services and tests could be purchased.

The program prototype selected was one for which providers ,able to satisfy the following criteria could apply for designation by the Department as an approved DES Diagnostic Center:

1. The availability of experienced and adequate personnel, equipment and laboratory support to carry out the recommendations outlined in the Physician's Advisory - Health Effects of the Pregnancy Use of Diethylstilbestrol.

2. The availability of personnel and equipment required to provide diagnostic evaluations for clear-cell adenocarcinoma.

3. The availability of personnel skilled in pathological analysis.

4. The availability of personnel skilled and experienced in the use of the colposcope.

5. The availability of personnel with demonstrated experience in the diagnostic evaluation of DES daughters.

6. The availability of a team inclusive of, but not limited to, a gynecologist, social worker or mental health professional, and medical and nursing personnel, for client support and counseling services. Team members should be skilled in counseling the DES daughter and knowledgeable of resources for referral when needed. Evidence of a referral mechanism for the DES daughter must be presented if these resources are not available on-site.

An informational booklet outlining the Department's responsibilities and those of any provider wishing to become an approved DES Center was developed and provided to all applicants.

Site visits were made to certain medical centers after formal application was made requesting approval by the Department. At this writing, the entire process has been completed and approval granted to seven centers (Table 5). Five of the centers are providing services to DES daughters through the Department's program, and two are in the process of establishing the program.

As the major focus of the program is to assure financial access to care to DES daughters, the establishment of a reimbursement mechanism with each facility is a key feature. That is, if a DES daughter does not have access to private health insurance or to Medicaid coverage, the Department will provide reimbursement to the center for appropriate services and tests. The Department is the "payer of last resort", but this assures that women in need of quality, specialized DES diagnostic evaluations will in fact receive them. Thus, equal access to DES services to Massachusetts DES daughters is assured, regardless of financial status.

To date, 28 women have been evaluated through the program. This sample is still too small to make any long-term predictions. However, with this in mind, the following profile of women evaluated was gleaned from the 23 records available to us.

The ages ranged from 13 to 40 years with the following breakdown:

Ages	Number
13-19	4
20-25	6
26-30	3
31-35	9
35-40	1

Fifteen of the women were listed as self-referrals; the remaining eight listed a private physician as a health care provider.

Follow-up recommendations were made for all the patients. Twelve women were advised to return to the center in one year; five women were advised to return to private physicians in one year; three women were advised to return to the center in six months; two women were advised to return to the center in three months; and one child was advised to return to the center at onset of menarche.

TABLE 5

Status of DES Diagnostic Program
Developed by Family Health Services, Jan. 10, 1983.

Facility	Application Approval Date	Actual "Start-Up" Date	Appointment No.
Eastern Mass.			
Beth Israel Hospital Boston, MA	7/13/82	9/13/82	(617) 735-3722
Brigham and Women's Hospital Boston, MA	Pending	Pending	—
Children's Hospital Medical Center Boston, MA	9/14/82	1/1/83	(617) 735-7648
Mass. General Hospital Boston, MA	8/9/82	11/16/82	(617) 726-8883
Central Region			
U. Mass. Medical Center Worcester, MA	8/23/82	9/20/82	(617) 856-3107
Worcester Hahnemann Hospital Worcester, MA	7/19/82	8/18/82	(617) 757-7751 ext. 559
Western Region			
Baystate Medical Center - Wesson Women's Springfield, MA	1/1/83	Pending	—

V. PROFESSIONAL EDUCATION ACTIVITIES

To publicize the DES Program to health care providers, Maternal and Child Health Services of the Division of Family Health Services prepared a letter announcing the development of a system of services to DES daughters, and distributed it widely to physicians listed as members of the American College of Obstetrics and Gynecology, hospitals known to provide obstetrical and/or gynecological services, neighborhood health centers, family planning centers, Special Supplemental Food Programs for Women, Infants and Children (WIC), and Maternal, Infants and Children, and Children and Youth Projects. A similar mailing is planned for pediatricians and family practitioners.

Also in the planning stages are educational programs for physicians and nurses. A small workgroup was convened to provide direction for this effort. A meeting was held with a representative of the Massachusetts Medical Society, at which time a liaison physician, Thomas Leavitt, M.D., was appointed as consultant for planning the programs for physicians.

A two-pronged approach was decided upon, consisting of the development of a Speaker's Bureau composed of recognized experts in the field who will present current DES information at hospital "rounds" and other regional professional meetings; and professional conferences for physicians and nurses co-sponsored by the Department, the Medical Society and, possibly, the American Cancer Society. The Speaker's Bureau will allow for wide dissemination of information to many more physicians and nurses than may be able to attend a major conference.

Tha plan for this first year is to develop a separate conference for nurses and physicians. The conference for physicians will be planned on a regional basis, using leaders of the DES Diagnostic Centers to plan according to the needs of the physicians in each region. The conferences are planned for the fall of 1983.

Conferences for nurses will be similarly planned. It has not yet been determined if there will be one major conference, or if regional conferences are feasible.

If possible, a program devoted to DES exposure will be presented at the annual meeting of the Massachusetts Medical Society in the spring of 1984.

Projected costs for professional education are: nurses conferences, $500 to $750; physicians conferences, $1,000 to $1,500; and Speaker's Bureau, $750. Total projected costs are $1,500 to $2,000.

VI. RECOMMENDATIONS

This report summarizes the Department's efforts over the past year in the development of a program of public education and diagnostic services for persons exposed to the drug DES. The first year of program operation has demonstrated that a need exists for accurate public information on DES, as well as a need to provide access to reliable diagnostic services for those at risk for exposure. The involvement of the medical community in this effort is a fundamental goal which has been achieved.

The volume of telephone and mail inquiries that result from our public service announcements and printed materials reflects the fact that we are meeting a specific need of the public. As the diagnostic service component continues to collect data on client characteristics, we will learn more about the affected population in Massachusetts. As a result, we will be in a much better position to expand and refine a program that serves the needs of the population at risk.

In light of our experience over the past 12 months, as summarized in the preceding chapters, we recommend that:

- the Department's program of public education, professional training and diagnostic services be continued at the current level of operation;

- funding be continued at the following levels:
  public information/education: $40,000 (Division of Preventive Medicine)
  diagnostic services: $50,000 (Division of Family Health Services);

- utilization of the diagnostic services component should be monitored during the program year to determine if funds are adequate to subsidize service demand;

- the Advisory Board continue to function in its present capacity in overall program planning and review;

- attention be focused on the identification of at least one diagnostic site to provide specialized consultation and services for DES-exposed males; and

- one or more existing diagnostic service centers be expanded to provide specialized services for DES mothers administered DES during pregnancy.